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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Translation

10/501259

PCT Application
PCT/JP2003/000089

| | | |
|---|---|--|
| Applicant's or agent's file reference 0224 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/JP03/00089 | International filing date (day/month/year) 08 January 2003 (08.01.03) | Priority date (day/month/year) 11 January 2002 (11.01.02) |
| International Patent Classification (IPC) or national classification and IPC C12N 15/12, C07K 14/515, C12Q 1/68, G01N 33/566, A61K 45/00, 38/17, 48/00, A61P 29/00 | | |
| Applicant SHIOZAWA, Shunichi | | |

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
 These annexes consist of a total of _____ sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 29 May 2003 (29.05.03) | Date of completion of this report 30 October 2003 (30.10.2003) |
| Name and mailing address of the IPEA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

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International application No.

PCT/JP03/00089

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 4-5,7-9

because:

- ☒ the said international application, or the said claims Nos. 4-5,7-9 relate to the following subject matter which does not require an international preliminary examination (*specify*):

SEE SUPPLEMENTAL SHEET

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 4-5,7-9.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

Claims 4-5 and 7-9 relate to methods for diagnosis or treatment practised on the human body, and thus relate to subject matter which does not require international preliminary examination by this International Preliminary Examining Authority, under the provisions of PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|------------|-----|
| Novelty (N) | Claims | 6, 10 | YES |
| | Claims | 1-3 | NO |
| Inventive step (IS) | Claims | 6, 10 | YES |
| | Claims | 1-3 | NO |
| Industrial applicability (IA) | Claims | 1-3, 6, 10 | YES |
| | Claims | | NO |

2. Citations and explanations

- Document 1: Database GenBank Accession No. U83508, 26 March 1997, Cell, 1996, 87 (7), pp. 1161-9
- Document 2: WO 00/64946 A2 (Board of Regents, The University of Texas System), 2 November 2000
- Document 3: WO 96/31598 A1 (Regeneron Pharmaceuticals, Inc.), 10 October 1996
- Document 4: WO 00/02587 A1 (Board of Regents, The University of Texas System), 20 January 2000

The inventions set forth in claims 1-3 are not novel and do not involve an inventive step in the light of documents 1-4 above, cited in the international search report.

Documents 1-4 disclose human angiopoietin-1 comprising an amino acid sequence 100% the same as the amino acid sequence represented by SEQ ID NO: 1 in the present application, and a nucleotide sequence for said human angiopoietin-1 which has 100% similarity with the nucleotide sequence represented by SEQ ID NO: 2 in the present application.

The inventions set forth in claims 6 and 10 involve an inventive step relative to documents 1-4.

Documents 1-4 do not disclose the possibility of

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assessing the possibility of developing chronic rheumatoid arthritis from the presence or absence of "GGT" as bases 805-807 in the nucleotide sequence represented by SEQ ID NO: 2 in the present application, and this feature could not be deduced easily by a person skilled in the art from documents 1-4.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

| <u>Application No. Patent No.</u> | <u>Publication date (day/month/year)</u> | <u>Filing date (day/month/year)</u> | <u>Priority date (valid claim) (day/month/year)</u> |
|---------------------------------------|--|---|---|
| WO 02/55692 A2 [EX] | 18 July 2002 (18.07.2002) | 09 January 2002 (09.01.2002) | 09 January 2001 (09.01.2001) |

2. Non-written disclosures (Rule 70.9)

| <u>Kind of non-written disclosure</u> | <u>Date of non-written disclosure (day/month/year)</u> | <u>Date of written disclosure referring to non-written disclosure (day/month/year)</u> |
|---------------------------------------|--|--|
|---------------------------------------|--|--|